Supreme Court, U.S.
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IN THE

Supreme Court of the United States

RX DEPOT, INC.; RX OF CANADA, LLC;
CARL MOORE; DAVID PEOPLES,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

FRED E. STOOPS, SR.
STOOPS LAW, P.L.L.C.
400 Riverwalk Terrace
Suite 250
Jenks, OK 74037
(918) 518-5230

STEVEN K. BALMAN
Counsel of Record
SNEED LANG, P.C.
1700 Williams Center,
Tower I
One West Third Street
Tulsa, OK 74103-3522
(918) 583-3145

Attorneys for Petitioners

201328

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTIONS PRESENTED

(1) Whether disgorgement of profits is a remedy available for violation of the Federal Food, Drug and Cosmetic Act?

(2) Whether the Court should overrule *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946), and *Mitchell v. Robert De Mario Jewelry, Inc.*, 361 U.S. 288 (1960), on the ground that they impermissibly enlarge the equitable jurisdiction of the federal courts?

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioners RX Depot, Inc. and RX of Canada, LLC state that they have no parent companies and no publicly held company owns 10% or more of their stock.

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The Petitioners, RX Depot, Inc., RX of Canada, LLC, Carl Moore and David Peoples respectfully pray that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Tenth Circuit, entered in the above-entitled proceeding on February 22, 2006.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 438 F.3d 1052, and is reprinted in the appendix hereto, p. 1a, *infra*.

The order of the United States District Court for the Northern District of Oklahoma is reported at 297 F. Supp. 2d 1306, and is reprinted in the appendix hereto, p. 23a, *infra*. A related order is reported at 290 F. Supp. 2d 1238, and is reprinted in the appendix hereto, p. 32a.

JURISDICTION

Invoking federal jurisdiction under 28 U.S.C. §§ 1331, 1337 and 1345 and 21 U.S.C. § 332(a), the respondent brought this suit in the Northern District of Oklahoma. The parties signed a consent decree of preliminary injunction that prohibited petitioners from facilitating the export of prescription drugs from Canada to the United States. *See* pp. 32a-33a, *infra*. On November 4, 2004, the Northern District denied the respondent's motion for disgorgement of profits. *See* p. 31a, *infra*.

Respondent appealed the denial of its disgorgement motion. On February 22, 2006, the Tenth Circuit entered a judgment and opinion reversing the district court's denial of disgorgement and remanding the matter for further proceedings. *See* p. 22a, *infra*. No petition for rehearing was sought.

The jurisdiction of this Court to review the judgment of the Tenth Circuit is invoked under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

21 U.S.C. § 332(a): "The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of [the Federal Food, Drug and Cosmetics Act]." *See* p. 4a, *infra.*

STATEMENT OF THE CASE

Federal courts are courts of limited jurisdiction. They have no inherent equitable powers, independent of the statutes they enforce. Petitioners submit that the equitable remedy of disgorgement is not available to respondents under Section 332(a) of the Federal Food, Drug and Cosmetic Act (the "FDCA").

Petitioners facilitated the sale of low cost prescription drugs from Canada to customers in the United States. *See* p. 37a, *infra.* The respondent brought suit against petitioners alleging their business practices violated provisions of the FDCA. Petitioners admitted to violating the FDCA and entered into a consent decree of permanent injunction. Later, the respondent sought disgorgement of petitioners' profits. The district court denied disgorgement, concluding it was not an available remedy under the FDCA as a matter of law. On the theory that the FDCA invokes courts' general equity jurisdiction and does not prohibit disgorgement by clear legislative command or necessary and inescapable inference, the Tenth Circuit reversed and remanded. *See* pp. 18a, 19a, & 22a, *infra.*

The Tenth Circuit relied upon Section 332(a) of the FDCA, and concluded that the power to "restrain violations" of the FDCA was a grant of general equitable jurisdiction—a grant that included both "forward-looking", prospective equitable remedies (*e.g.*, injunctions) and "backward-looking", retrospective equitable remedies (*e.g.*, disgorgement of profits). *See* p. 11a-12a, *infra.* The Tenth Circuit also based its conclusion that the power to "restrain violations" is the power to order

disgorgement of profits on two cases—*Porter v. Warner Holding Co.*, 328 U.S. 395 (1946), and *Mitchell v. Robert De Mario Jewelry, Inc.*, 361 U.S. 288 (1960). *See* 4a-6a, *infra*. *Porter* and *Mitchell* both interpreted similar language in other federal statutes to authorize "backward-looking" equitable remedies not specifically mentioned in the statutes.

REASONS FOR GRANTING THE PETITION

I.

There is a conflict among the circuits with respect to the availability of disgorgement as a remedy under the FDCA. The Tenth Circuit's opinion in this case conflicts with the Ninth Circuit's opinion in *United States v. Parkinson*, 240 F.2d 918 (9th Cir. 1956) (no restitution remedy under FDCA). The Food and Drug Administration ("FDA") did not ask for the remedy of disgorgement for over 40 years after the Ninth Circuit's decision in *Parkinson*. *See* William W. Vodra & Arthur N. Levine, *Anchors Away: The Food and Drug Administration's Use of Disgorgement Abandons Legal Moorings*, 59 FOOD & DRUG L.J. 1, 2 at 5-6 (2004). *See United States v. Ten Cartons of Ener-B Nasal Gel*, 888 F. Supp. 381, 404-405 (E.D.N.Y. 1995), *aff'd on other grounds*, 72 F.3d 285 (2d Cir. 1995).[1] *See also United States v. Universal Mgmt. Servs., Inc.*, 999 F. Supp. 974, 980-81 (N.D. Ohio 1997) (denying FDA's request for disgorgement but awarding restitution as part of injunction), *aff'd*, 191 F.3d 750, 760-62 (6th Cir. 1999) (expansive interpretation of FDCA). *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 225 (3d Cir. 2005) (same).

1. The FDA did not seek the backward-looking remedies of disgorgement or restitution during the first thirteen years after the enactment of the FDCA. *See* Note, *Restitution in Food and Drug Enforcement*, 4 STAN. L. REV. 519, 521 (1951-1952). When the FDA finally sought disgorgement/restitution for the first time in 1951, the effort was short-lived. The first case ended in a settlement that did not include either restitution or disgorgement. *Id.* at 521.

II.

No district court has ever ordered disgorgement of profits under Section 332(a) of the FDCA. Disgorgement is an extra-statutory remedy. The disgorgement remedy is not authorized by the plain language of Section 332(a). The authority to order disgorgement is derived by a two stage process of statutory interpretation. In stage one, the plain language of the statute—the grant of authority to "restrain violations" of the FDCA—is interpreted to invoke the general equity jurisdiction of the federal courts. *See* p. 11a, *infra*. In stage two, the general equity jurisdiction of the federal courts is deemed to include the power to award disgorgement, an equitable remedy. *Id.*

The two stage approach to statutory interpretation is taken from two cases—*Porter* and *Mitchell*. Though neither *Porter* nor *Mitchell* involved the FDCA, both involved the "restrain violations" language used in the FDCA. Significantly, *Porter* and *Mitchell* are inconsistent with the notion that statutes should be interpreted in accordance with their plain language. *See Exxon Mobil Corp. v. Allapattah Services, Inc.*, __ U.S. __, 125 S. Ct. 2611, 2626 (2005).[2] The phrase "restrain violations" is forward-looking. "Restrain" means "to prevent from doing, exhibiting, or expressing something." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 999 (5th ed. 1999) (meaning 1a). It does not mean "to punish." Disgorgement is a punitive remedy. *See, e.g., Parkinson*, 240 F.2d at 921-922 (invoking the spectre of the

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2. *See* Erika King & Elizabeth M. Walsh, *The Authority of a Court to Order Disgorgement for Violations of the Current Good Manufacturing Requirement of the Federal Food Drug and Cosmetic Act*, 58 FOOD & DRUG L. J. 149, 159-160 (2003) (discussing recent legislative history of FDCA as evidence that Congress did not intend disgorgement to be a remedy). Ample statutory remedies are available. There is no need to resort to extra-statutory remedies. *Id.* at 163.

Star Chamber, "of unhappy memory") ("the spirit of equity abhorred punitive measures").[3] *See also Hygrade Food Prods. Corp. v. United States*, 160 F.2d 816, 819 (8th Cir. 1947) (Injunctive relief under Section 332(a) "is primarily a preventative remedy; it looks to the future rather than the past. It is not for the purpose of punishing wrongful acts already committed.")

Porter and *Mitchell* are also inconsistent with this Court's recent decisions prohibiting the use of extra-statutory remedies. *See Mehrig v. KFC Western, Inc.*, 516 U.S. 479, 487-488 (1996) (RCRA does not encompass backward-looking monetary relief such as equitable restitution or disgorgement), *followed in United States v. Philip Morris USA Inc.*, 396 F.3d 1190, 1198-1200 (D.C. Cir. 2005) (no disgorgement remedy under RICO). *And see Alexander v. Sandoval*, 532 U.S. 275, 287 (2001) (extra-statutory private rights of action are not presumed or readily found to exist). ("Having sworn off the habit of venturing beyond Congress's intent, we will not accept respondents' invitation to have one last drink.") With respect, the federal courts should "swear off the habit" of creating extra-statutory remedies.

The FDA apparently intends to ask for the disgorgement remedy more frequently. *See* Eric M. Blumberg, *Universal Management, Abbott, Wyeth, Schering-Plough, and . . . : Restitution and Disgorgement Find Another Home at the Food and Drug Administration*, 58 Food & Drug L.J. 169 (2003) (article by FDA litigation counsel). The Tenth Circuit's opinion will only encourage the expanded and increased use of the disgorgement remedy, a remedy that was never intended by Congress. The Tenth Circuit's opinion will only encourage federal agencies to find new and creative ways to exceed their legislative mandates by invoking the equitable jurisdiction of the federal courts.

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3. There is no evidence that any of respondents' customers suffered any financial loss. *See* p. 37a, *infra*.

The Tenth Circuit rewrites the text of the FDCA to enlarge the jurisdiction of the federal courts. Courts may not rewrite statutes. *See, e.g., PGA Tour, Inc. v. Martin*, 535 U.S. 661, 692 (2001) (Scalia and Thomas, JJ., dissenting).

CONCLUSION

For these various reasons, this petition for certiorari should be granted.

Respectfully submitted,

FRED E. STOOPS, SR.
STOOPS LAW, P.L.L.C.
400 Riverwalk Terrace
Suite 250
Jenks, OK 74037
(918) 518-5230

STEVEN K. BALMAN
Counsel of Record
SNEED LANG, P.C.
1700 Williams Center,
Tower I
One West Third Street
Tulsa, OK 74103-3522
(918) 583-3145

Attorneys for Petitioners

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT FILED FEBRUARY 22, 2006

UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

No. 05-5003

UNITED STATES OF AMERICA,

Plaintiff-Counter-
Defendant-Appellant,

v.

RX DEPOT, INC., corporation; RX OF CANADA, LLC, corporation; CARL MOORE, individual; DAVID PEOPLES, individual,

Defendants-Counter-
Claimants-Appellees.

WASHINGTON LEGAL FOUNDATION,

Amicus Curiae.

Before **HENRY**, **McWILLIAMS** and **MURPHY**, Circuit Judges.

MURPHY, Circuit Judge.

Appendix A

I. Introduction

Appellees Rx Depot, Inc., Rx of Canada, LLC, Carl Moore, and David Peoples (collectively "Rx Depot") facilitated the sale of prescription drugs from Canada to customers in the United States. The United States brought suit against Rx Depot, alleging its business practices violated provisions of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-397. Rx Depot admitted to violating the Act and entered into a consent decree of permanent injunction. Subsequently, the United States sought disgorgement of Rx Depot's profits. The district court denied disgorgement, concluding it was not an available remedy under the FDCA as a matter of law. We exercise jurisdiction pursuant to 28 U.S.C. § 1291. Because the FDCA invokes courts' general equity jurisdiction and does not prohibit disgorgement by clear legislative command or necessary and inescapable inference, we **reverse** and **remand**.

II. Background

Rx Depot helped consumers in the United States obtain prescription drugs from Canada at reduced prices. A customer with a prescription from an American physician could download forms from Rx Depot's website or visit one of Rx Depot's storefront affiliates to order medications. Rx Depot then transmitted the customer's forms, prescription, and payment information to cooperating Canadian pharmacies. A Canadian physician would rewrite the prescription, which was then filled by a Canadian pharmacy and sent directly to the customer in the United States. Rx Depot received a ten to twelve percent commission for each sale they facilitated.

Appendix A

The United States filed a civil action alleging Rx Depot's activities violated provisions of the FDCA. Specifically, the government alleged Rx Depot violated § 381(d)(1) by reimporting prescription drugs originally manufactured in the United States and § 355(a) by introducing new drugs into interstate commerce without FDA approval. The government sought a temporary and permanent injunction and other equitable relief. The district court entered a preliminary injunction ordering Rx Depot to discontinue its business activities. The parties then agreed to, and the district court approved, a consent decree of permanent injunction. In the consent decree, Rx Depot admitted to violating the FDCA and agreed not to resume its business operations. The consent decree left "to the discretion of [the district court] the issue of what, if any, equitable relief, including restitution and/or disgorgement, should be awarded to [the United States]."

Subsequently, the district court denied restitution, reasoning Rx Depot's customers did not lose money in their transactions because they purchased medications at reduced prices. The district court initially concluded disgorgement would be an appropriate remedy. Upon reconsideration, however, the district court determined disgorgement was not available under the FDCA as a matter of law. Although the FDCA invokes courts' equity jurisdiction, the district court determined the Act's express provision of other remedies and legislative history create a necessary and inescapable inference that Congress intended to restrict courts' power to order disgorgement. The United States appeals only the district court's denial of disgorgement.

III. Discussion

We review questions of statutory interpretation *de novo*. *Employers Reinsurance Corp. v. Mid-Continent Cas. Co.*, 358 F.3d 757, 774 (10th Cir.2004). The FDCA provides, "[t]he district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of [the FDCA]." 21 U.S.C. § 332(a). The issue before this court is whether this statutory grant of jurisdiction enables district courts to order disgorgement in appropriate cases.

In *Porter v. Warner Holding Co.*, the Supreme Court held when Congress invokes the equity jurisdiction of courts in a statute, "all the inherent equitable powers of the [courts] are available for the proper and complete exercise of that jurisdiction," unless the statute, by "clear and valid legislative command" or "necessary and inescapable inference," restricts the forms of equitable relief authorized. 328 U.S. 395, 398, 66 S.Ct. 1086, 90 L.Ed. 1332 (1946). The Court in *Porter* was examining whether § 205(a) of the Emergency Price Control Act of 1942 ("EPCA")[1] permitted federal courts to

1. Section 205(a) provided:

> [T]he Administrator [of the Office of Price Administration] may make application to the appropriate court for an order enjoining . . . acts or practices [in violation of the statute] . . . and upon a showing by the Administrator . . . [of] such acts or practices a permanent or temporary injunction, restraining order, or other order shall be granted without bond.

Emergency Price Control Act of 1942, § 205(a), 56 Stat. 23, 33.

order restitution of rents collected in excess of statutory maximums. *Id.* at 396, 66 S.Ct. 1086. The Court determined restitution was authorized by the statute because § 205(a) invoked courts' general equity jurisdiction and the statute did not expressly or impliedly preclude restitution. *Id.* at 397-98, 403, 66 S.Ct. 1086. Moreover, the Court noted because the suit involved the public interest and not merely a private controversy, courts' "equitable powers assume[d] an even broader and more flexible character." *Id.* at 398, 66 S.Ct. 1086.

Arguably, the Court's decision in *Porter* also relied in part on the broad language of § 205(a), which authorized "any . . . other order." *See id.* at 399, 66 S.Ct. 1086. The Court's subsequent decision in *Mitchell v. Robert De Mario Jewelry, Inc.*, however, demonstrates that such inclusive language is not required. 361 U.S. 288, 291, 80 S.Ct. 332, 4 L.Ed.2d 323 (1960); *see also Atchison, Topeka & Santa Fe Ry. Co. v. Lennen*, 732 F.2d 1495, 1506 (10th Cir.1984). In *Mitchell*, the Court determined the Fair Labor Standards Act ("FLSA") authorizes federal courts to order reimbursement of lost wages to employees who are discriminated against or unlawfully discharged for filing complaints under the Act. *Id.* at 296, 80 S.Ct. 332. The Court relied exclusively on language in the statute granting courts authority "for cause shown, to restrain violations of [the FLSA]." *Id.* at 289, 291, 80 S.Ct. 332. The Court observed that the absence of language in the statute affirmatively confirming the power of courts to order reimbursement did not preclude such relief in light of the statute's grant of general equity jurisdiction. *Id.* at 291, 80 S.Ct. 332. The Court explained, "[w]hen Congress entrusts to an equity court the enforcement of prohibitions contained

in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in the light of statutory purposes." *Id.* at 291-92, 80 S.Ct. 332. Accordingly, under *Porter* and *Mitchell*, when a statute invokes general equity jurisdiction, courts are permitted to utilize any equitable remedy to further the purposes of the statute absent a clear legislative command or necessary and inescapable inference restricting the remedies available.

Amicus argues our analysis of the remedies available under the FDCA should be guided by *Meghrig v. KFC Western, Inc.* instead of *Porter* and *Mitchell*. *Meghrig*, 516 U.S. 479, 116 S.Ct. 1251, 134 L.Ed.2d 121 (1996). *Meghrig* held the grant of general equity jurisdiction in the Resource Conservation and Recovery Act's ("RCRA") citizen suit provision[2] does not authorize courts to order restitution of past cleanup costs. *Id.* at 487, 116 S.Ct. 1251. The plaintiff in *Meghrig* owned property contaminated with petroleum products. *Id.* at 481, 116 S.Ct. 1251. After having the waste removed and disposed of, the plaintiff brought suit against a former property owner seeking recovery of cleanup costs the plaintiff had expended. *Id.* at 481-82, 116 S.Ct. 1251. In concluding the remedy was not available under RCRA, the Court recognized, but did not overrule, *Porter's* and *Mitchell's* holding that a statutory grant of general equity

2. RCRA's citizen suit provision authorizes district courts "to restrain any person who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste . . . , to order such person to take such other action as may be necessary, or both. . . ." 42 U.S.C. § 6972(a).

jurisdiction authorizes courts to use all traditional equitable powers. *Id.* at 487, 116 S.Ct. 1251; *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496, 121 S.Ct. 1711, 149 L.Ed.2d 722 (2001) (citing *Porter* in a case decided after *Meghrig* for the proposition that courts sitting in equity "have discretion unless a statute clearly provides otherwise"); *Miller v. French*, 530 U.S. 327, 340-41, 120 S.Ct. 2246, 147 L.Ed.2d 326 (2000) (same). Instead, the Court merely identified RCRA as a statute that fit into the exceptions recognized by *Porter* and *Mitchell. Meghrig*, 516 U.S. at 487, 116 S.Ct. 1251. In particular, the Court determined RCRA contained a clear legislative command and concluded Congress did not intend to permit recovery of past cleanup costs. *Id.* at 484-88, 116 S.Ct. 1251. The Court also determined the recovery of past cleanup costs was not consistent with the statutory purposes of RCRA. *Id.* at 483, 116 S.Ct. 1251.

First, the Court reasoned the clear language of RCRA's citizen suit provision precludes an order of restitution for past cleanup costs. *Id.* at 486, 116 S.Ct. 1251. RCRA's citizen suit provision permits suit "against any person . . . who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste which may present an imminent and substantial endangerment to health or the environment. . . ." 42 U.S.C. § 6972(a)(1)(B). The Court observed that the requirement that waste "*may present* an *imminent* . . . endangerment" demonstrated the provision was directed only at harm that threatens to occur in the immediate future. *Meghrig*, 516 U.S. at 485-86, 116 S.Ct. 1251 (emphasis added). Thus, it concluded, costs for the *past*

cleanup of waste that no longer poses a danger to health or the environment are not recoverable. *Id.*

Second, the Court found evidence that Congress did not intend to authorize restitution of past cleanup costs in both the structure of RCRA and its relation to another environmental statute. RCRA prohibits citizen suits when either the EPA or the State has commenced a separate enforcement action. 42 U.S.C. § 6972(b)(2)(B) & (C). Thus, if RCRA permitted restitution for past cleanup costs, it would only provide compensation in those cases in which waste problems are not severe or substantial enough to attract governmental attention. *Meghrig*, 516 U.S. at 486-87, 116 S.Ct. 1251. The Court rejected this result as wholly irrational, concluding Congress could not have intended to provide compensation for individuals with minor waste problems while leaving individuals with severe or substantial waste problems without a remedy. *Id.*

The Court's analysis also relied on significant differences between RCRA and the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"). CERCLA, which was enacted several years after RCRA, contains a citizen suit provision which mimics RCRA's and authorizes courts "to order such action as may be necessary to correct" violations of the Act. *Id.* at 485, 116 S.Ct. 1251. Unlike RCRA, however, CERCLA also contains an explicit provision permitting the recovery of remediation costs. *Id.* (citing 42 U.S.C. § 9607(a)(4)(B)). The Court concluded the absence of similar language in RCRA compelled an inference—that Congress did not intend to provide past cleanup costs under RCRA because it would have been unnecessary for

Congress to specifically enumerate the remedy in CERCLA if it was already encompassed within the statute's grant of general equity jurisdiction. *Id.* at 485, 487, 116 S.Ct. 1251.

Finally, the Court noted an award of past cleanup costs is inconsistent with RCRA's purposes. *Id.* at 483, 116 S.Ct. 1251. The primary purposes of RCRA, according to the Court, are to reduce the generation of hazardous and solid waste and ensure its proper treatment, storage, and disposal, not to effectuate the cleanup of waste sites or to compensate those who have remediated waste sites. *Id.*

Thus, rather than overruling or limiting *Porter's* and *Mitchell's* general rule that a grant of equity jurisdiction enables courts to order any form of equitable relief, *Meghrig* merely demonstrates that a statute's particular characteristics may preclude application of the rule. *See Meghrig*, 516 U.S. at 487, 116 S.Ct. 1251. Additionally, *Meghrig* is distinguishable from the present case, and from *Porter* and *Mitchell*, because it involved a controversy between private parties relying on a statutory provision for private causes of action, not an enforcement action by the government to protect the public. As the Court pointed out in *Porter*, "equitable powers assume an even broader and more flexible character" in suits involving the public interest. 328 U.S. at 398, 66 S.Ct. 1086. Thus, *Meghrig's* restrictive view of the remedies available under RCRA's citizen suit provision is likely due in part to the private nature of actions brought under the provision. *See United States v. Price*, 688 F.2d 204, 213-14 (3d Cir.1982) (observing that 42 U.S.C. § 6973, a RCRA provision which authorizes the EPA to bring suit to restrain violations of the Act, confers upon courts broad authority to grant equitable relief). For these reasons, the

general rule announced in *Porter*, and followed by *Mitchell* and *Meghrig*, guides our analysis.[3]

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3. Amicus contends that by implying additional remedies in a statute where Congress authorized only specified forms of relief, *Mitchell* exemplifies the type of analysis the Supreme Court once employed in implying private rights of action. Amicus notes that the Supreme Court abandoned implying private rights of action in *Alexander v. Sandoval*, and argues the Court similarly abandoned implying equitable remedies in *Meghrig*. *Sandoval*, 532 U.S. 275, 121 S.Ct. 1511, 149 L.Ed.2d 517 (2001); *Meghrig v. KFC Western, Inc.*, 516 U.S. 479, 116 S.Ct. 1251, 134 L.Ed.2d 121 (1996). As discussed above, *Meghrig* did not overrule or limit *Porter* and *Mitchell*. *Mitchell v. Robert De Mario Jewelry, Inc.*, 361 U.S. 288, 80 S.Ct. 332, 4 L.Ed.2d 323 (1960); *Porter v. Warner Holding Co.*, 328 U.S. 395, 66 S.Ct. 1086, 90 L.Ed. 1332 (1946). To the extent amicus argues *Sandoval* should persuade this court that the reasoning of *Porter* and *Mitchell* have been abandoned by the Supreme Court, we disagree. The line of cases from *J.I. Case Co. v. Borak* to *Sandoval* discusses the circumstances in which courts should imply a right of action allowing private parties to sue to enforce a statute when the statute itself does not explicitly authorize any such action. *J.I. Case*, 377 U.S. 426, 431-33, 84 S.Ct. 1555, 12 L.Ed.2d 423 (1964), *abrogated by Sandoval*, 532 U.S. 275, 121 S.Ct. 1511, 149 L.Ed.2d 517 (implying private right of action because it effectuated the purpose of the statute); *Sandoval*, 532 U.S. at 293, 121 S.Ct. 1511 (refusing to imply private right of action where there was no evidence Congress intended to provide one). These cases are not applicable here for two reasons. First, we are not being asked to imply a private right of action under the FDCA. Second, while the statutes at issue in *J.I. Case* and *Sandoval* did not explicitly authorize private rights of action, the FDCA, and the statutes at issue in *Porter*, *Mitchell*, and *Meghrig*, contain an explicit grant of general equity jurisdiction. Although that grant does not enumerate all available forms of equitable relief, a general grant of equity jurisdiction has long been

(Cont'd)

Appendix A

Section 332(a) of the FDCA invokes the equity jurisdiction of courts using the same statutory language the Supreme Court construed in *Mitchell* to authorize all traditional equitable remedies. *Compare* 21 U.S.C. § 332(a) ("district courts . . . shall have jurisdiction, for cause shown to restrain violations"), *with* 29 U.S.C. § 217 ("district courts . . . shall have jurisdiction, for cause shown, to restrain violations"); *see Mitchell*, 361 U.S. at 289, 291-92, 80 S.Ct. 332. Disgorgement is a traditional equitable remedy. *FTC v. Gem Merch. Corp.*, 87 F.3d 466, 469 (11th Cir.1996). Moreover, because the present action was brought by the government to protect the public health and safety, courts' equitable jurisdiction under the statute "assume[s] an even broader and more flexible character." *Porter*, 328 U.S. at 398, 66 S.Ct. 1086. Thus, disgorgement is available under the FDCA unless (1) there is a clear legislative command or necessary and inescapable inference prohibiting disgorgement or (2) disgorgement is inconsistent with the purposes of the FDCA.

Rx Depot and amicus first contend the text of the FDCA limits the remedies available under the Act to forward-

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recognized as authorizing courts to employ all their traditional equitable powers. *See Porter*, 328 U.S. at 398, 66 S.Ct. 1086. Thus, there is a statutory anchor for the equitable remedies here that is not present in cases where private rights of action are implied. For these reasons, we decline amicus' invitation to construe broadly the reasoning of *Sandoval* as overruling dissimilar, long-standing precedent. *See State Oil Co. v. Khan*, 522 U.S. 3, 20, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997) ("it is th[e] [Supreme] Court's prerogative alone to overrule one of its precedents").

looking remedies. They argue the term "restrain" in § 332(a) envisions stopping ongoing violations of the Act or preventing future ones, not punishing past violations. Thus, they urge, the backward-looking remedy of disgorgement is expressly prohibited by the statute.

In *Mitchell*, the Supreme Court interpreted the statutory command "to restrain violations" to permit the arguably backward-looking remedy of restitution. 361 U.S. at 296, 80 S.Ct. 332; *see also Atchison*, 732 F.2d at 1506-07. Subsequently, in *Meghrig*, the Court observed that the term "restrain" in RCRA envisions forward-looking, prohibitory injunctions. 516 U.S. at 484, 116 S.Ct. 1251. In that case, however, the Court also relied heavily on other language expressed and implied in the statute in concluding restitution of past cleanup costs was not available. *See id.* at 483-87, 116 S.Ct. 1251. Moreover, the Court did not explicitly overrule *Mitchell's* holding that backward-looking remedies are permitted under a grant of authority to restrain violations. In light of these considerations, we do not think the presence of the term "restrain" in a statutory grant of general equity jurisdiction is dispositive evidence of Congress' intent to limit remedies to those that are forward-looking.[4]

4. It is not clear that disgorgement is solely a backward-looking remedy. One purpose of disgorgement is to deter future violations of the law by making illegal conduct unprofitable. *See Porter*, 328 U.S. at 400, 66 S.Ct. 1086. When disgorgement is ordered to prevent future violations of the law it is a forward-looking remedy. *See, e.g., SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1475 (2d Cir.1996) (noting primary purpose of disgorgement under federal securities laws is forward-looking deterrence); *United States v. Carson*, 52 F.3d

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Rx Depot and amicus also rely on *United States v. Philip Morris USA, Inc.* in arguing that a statutory grant of equity jurisdiction "to restrain violations" authorizes only forward-looking remedies. 396 F.3d 1190 (D.C.Cir.2005). In *Philip Morris*, a divided panel of the District of Columbia Circuit held disgorgement was not available under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-68. *Id.* at 1202. RICO authorizes district courts

> to prevent and restrain violations of [RICO] by issuing appropriate orders, including, but not limited to: ordering any person to divest himself of any interest, direct or indirect, in any enterprise; imposing reasonable restrictions on the future activities or investments of any person . . . ; or ordering dissolution or reorganization of any enterprise. . . .

18 U.S.C. § 1964(a). Citing *Meghrig*, the court reasoned the statutory language "to prevent and restrain" limited courts to ordering forward-looking remedies aimed at preventing future violations of the Act. *Id.* at 1199. *But see id.* at 1220-22 (Tatel, J., dissenting) (arguing that *Porter* and *Mitchell*, not *Meghrig*, control). The court also relied on the fact that the remedies enumerated in the statute's jurisdictional grant

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1173, 1182 (2d Cir.1995) (observing that disgorgement of recently acquired profits may serve forward-looking purpose of preventing future violations); *cf. United States v. Lane Labs-USA Inc.*, 427 F.3d 219, 229 (3d Cir.2005) (noting restitution is forward-looking because it can serve deterrent function).

are all forward-looking. Thus, the court applied the canons *noscitur a sociis* and *ejusdem generis* to conclude that any authorized remedies beyond those specifically mentioned in the statute must be similarly forward-looking. *Id.* at 1200. *But see id.* at 1224 (Tatel, J., dissenting) (questioning the applicability of the canons in light of the statute's command that the list of remedies is not exhaustive).

Although we express no opinion regarding whether, or in what circumstances, disgorgement is authorized under RICO, *Philip Morris* is inapposite to our decision here because the court relied on statutory language in RICO not present in the FDCA. *See id.* at 1199 ("In the RICO Act, Congress provided a statute granting jurisdiction defined with the sort of limitations not present in the FLSA or the EPCA."). In any event, we note that *Philip Morris* did not question the continued validity of *Porter* and *Mitchell*, the cases we rely on here. *See id.* at 1200 (ruling out disgorgement remedy using *Porter* test).[5]

Rx Depot and amicus next contend that because the FDCA explicitly authorizes certain remedies, we should be reluctant to infer additional remedies. Defendants and amicus fail to recognize that by granting courts general equity jurisdiction, Congress authorized all traditional equitable

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5. Two other circuits have concluded RICO does not categorically prohibit disgorgement. *See Richard v. Hoechst Celanese Chem. Group, Inc.*, 355 F.3d 345, 354-55 (5th Cir.2003); *Carson*, 52 F.3d at 1181. In both cases, however, the courts went on to determine disgorgement was not appropriate under the facts of the particular cases before them. *Richard*, 355 F.3d at 354-55; *Carson*, 52 F.3d at 1181-82.

remedies. As the Court noted in *Mitchell*, "[w]hen Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in the light of statutory purposes." 361 U.S. at 291-92, 80 S.Ct. 332. Thus, we need not infer any remedies; rather, all equitable remedies are available unless Congress' express provision of other remedies creates a necessary and inescapable inference that those remedies are exclusive.

In *Porter*, the Court determined the express provision of certain remedies in the EPCA did not create a necessary and inescapable inference limiting courts' authority to order unenumerated equitable remedies. 328 U.S. at 402, 66 S.Ct. 1086. In addition to general equity jurisdiction, the EPCA provided for criminal, civil, and administrative remedies. Specifically, individuals faced criminal fines and imprisonment for violations of the Act. EPCA, § 205(b), 56 Stat. 23, 33. Individuals injured by a violation of the Act could file a civil suit seeking treble damages plus attorneys' fees. *Id.* § 205(e), 56 Stat. at 34. If an individual was prevented from bringing a civil suit for various reasons, the Administrator of the Office of Price Administration ("Administrator") could sue for damages on behalf of the United States. *Id.* Finally, the Administrator had authority to suspend a violator's license. *Id.* § 205(f)(2), 56 Stat. at 35. Despite these express remedies, the Court in *Porter* concluded the grant of general equity jurisdiction in the EPCA was not restricted. *Porter*, 328 U.S. at 402, 66 S.Ct. 1086.

Appendix A

The express remedies provided in the FDCA are similar to those available under the EPCA. In addition to general equity jurisdiction, the FDCA explicitly provides for criminal, civil, and administrative remedies. *See* 21 U.S.C. § 333 (providing for criminal fines and imprisonment and civil monetary penalties); *id.* § 360h(b) & (e) (authorizing Secretary of Health and Human Services ("Secretary") to order recall, repair, replacement, or refund of purchase price for medical devices); *id.* § 350a(e)(1)(B) (authorizing Secretary to recall adulterated or misbranded infant formula); *id.* § 360pp(a) & (b) (granting district courts equity jurisdiction and providing for civil monetary penalties for violation of statutory provisions relating to electronic products). These remedies are no more expansive or comprehensive than those found in the EPCA. Seizure is the only express remedy provided for in the FDCA that was not also authorized by the EPCA. *Id.* § 334. This single additional remedy, however, does not create a necessary and inescapable inference that Congress intended to exclude all other remedies.

Amicus further argues the specific authorization of restitution for certain medical devices in one provision of the FDCA shows Congress did not intend to allow disgorgement under another provision of the Act. The FDCA permits the Secretary to order the manufacturer, importer, or distributor of a medical device found in violation of the Act to refund the purchase price of the device to customers. *Id.* § 360h(b)(2)(C). Before ordering a refund, the Secretary must determine that the device presents an unreasonable risk of substantial harm to the public health; there are reasonable grounds to believe the device is defective; the defect was

caused by the manufacturer, importer, distributor, or retailer; and other remedies are inadequate to eliminate the risk posed by the device. *Id.* § 360h(b)(1)(A). Amicus contends the detailed showing required to permit restitution is inconsistent with the view that Congress intended to provide for the similar remedy of disgorgement upon a mere showing of a violation of the Act.

This argument is unpersuasive. Section 360h describes only the Secretary's powers in administering the Act. The section says nothing about remedies that may be ordered by courts. We decline to read the FDCA's grant of expanded administrative powers as a diminishment of the federal courts' judicial powers under a grant of general equity jurisdiction. *See Porter*, 328 U.S. at 401-02, 66 S.Ct. 1086. This reading is especially unwarranted in light of § 360h(d), which specifically provides that "[c]ompliance with an [administrative refund order] shall not relieve any person from liability under Federal or State law." 21 U.S.C. § 360h(d).

Finally, Rx Depot argues the legislative history of the FDCA, which indicates that Congress intended seizure to be the harshest remedy available under the Act, precludes disgorgement. We are not convinced, however, that seizure is harsher than disgorgement in all circumstances. *See United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 762 (6th Cir.1999) (concluding restitution is not necessarily harsher than seizure). Procedurally, the seizure remedy permitted under the FDCA is arguably harsher than disgorgement. The FDCA permits administrative seizure on the basis of an *ex parte* showing of reasonable belief.

21 U.S.C. § 344(g). Disgorgement, on the other hand, is only permitted after a party is found by a court to be in violation of the Act and only at the court's discretion. Additionally, seizure is not necessarily harsher than disgorgement in terms of monetary loss to a company. Seizure of a company's inventory deprives the company of both capital investment and potential profit, whereas disgorgement only deprives a company of its profits. Although court-ordered disgorgement over an extended period of time may operate as a harsher remedy than a one-time seizure, the opposite is likely true for disgorgement ordered over a shorter time period. Thus, even if Congress intended seizure to be the harshest remedy available under the statute, it does not follow that Congress necessarily and inescapably intended to preclude disgorgement in all circumstances.

Because the FDCA does not contain a clear legislative command or compel a necessary and inescapable inference precluding disgorgement, an order of disgorgement is permitted if it furthers the purposes of the FDCA. *See Porter*, 328 U.S. at 400, 66 S.Ct. 1086; *Atchison*, 732 F.2d at 1507. The FDCA's primary purpose is to protect the public health. *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969). To be sure, the public health is protected not only by halting current violations of the Act, but also by deterring future violations. Disgorgement, which deprives wrongdoers of their ill-gotten gains, deters violations of the law by making illegal activity unprofitable. *SEC v. Fischbach Corp.*, 133 F.3d 170, 175 (2d Cir.1997). As the Court noted in *Porter*, "[f]uture compliance may be more definitely assured if one is compelled to restore one's illegal gains." 328 U.S. at 400,

66 S.Ct. 1086. Therefore, disgorgement furthers the purposes of the FDCA.

In sum, the FDCA invokes courts' general equity jurisdiction by authorizing courts "to restrain violations" of the Act. This broad grant of equity jurisdiction is not restricted by the text of the statute, its express provision of certain legal and administrative remedies, or its legislative history. Moreover, disgorgement furthers the purposes of the FDCA by deterring future violations of the Act which may put the public health and safety at risk. Therefore, according to the analysis established in *Porter* and *Mitchell*, we conclude disgorgement is permitted under the FDCA in appropriate cases.[6]

Our determination that disgorgement is authorized by the FDCA is supported by decisions in several other circuits. Although we are the first circuit to address disgorgement under the FDCA, two circuits have held recently that restitution is authorized by the Act. These decisions, and the analysis employed by the courts in reaching them, substantiate our reasoning here.

In *Universal Management*, the Sixth Circuit upheld an order of restitution requiring a party who sold adulterated

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6. Because the district court determined disgorgement was not available under the FDCA, it did not examine whether there were any ill-gotten gains to be disgorged or whether disgorgement was appropriate under the facts of this case. Therefore, we remand for the district court to address this issue in the first instance. *See R. Eric Peterson Constr. Co. v. Quintek, Inc. (In re R. Eric Peterson Constr. Co.)*, 951 F.2d 1175, 1182 (10th Cir.1991).

medical devices to provide refunds to its customers. 191 F.3d at 762. The court relied on *Porter* and *Mitchell* in refusing to interpret the FDCA as limiting the equitable jurisdiction of federal courts because it found no clear congressional intent to impose such a limit. *Id.* at 761-62. The court acknowledged there was some evidence of congressional intent that seizure should be the harshest remedy available under the Act, but concluded that such concerns were far from a clear statement from Congress to exclude restitution, especially when it was not clear that restitution is harsher than seizure in all circumstances. *Id.* at 762.

The Third Circuit similarly upheld the authority of courts to order restitution under the FDCA in a case involving misbranding of and failure to obtain FDA approval for dietary supplements and skin cream purported to prevent and treat cancer. *United States v. Lane Labs-USA Inc.*, 427 F.3d 219, 220 (3d Cir.2005). Applying *Porter* and *Mitchell*, the court determined that a district court sitting in equity may order restitution unless the statute clearly limits the court's equitable jurisdiction or restitution does not further the purposes of the statute. *Id.* at 225. The court found no evidence in the FDCA limiting equity jurisdiction. *Id.* at 226. Moreover, the court determined restitution furthered the purposes of the statute because it protected the financial interests of consumers and deterred individuals from violating the Act. *Id.* at 227, 229. The court also distinguished *Meghrig* and *Philip Morris*. Regarding *Meghrig*, the court noted that the Supreme Court's decision rested on explicit language in RCRA and the Act's elaborate remedial scheme, neither of which are present in the FDCA. *Id.* at 231-32. The court also observed that, unlike the case before it, *Meghrig*

did not involve an enforcement action by the government in which equitable powers are broader and more flexible. *Id.* at 231. Finally, the court noted that the "restitution" of past cleanup costs sought in *Meghrig* resembled traditional damages, and thus was different than the restitution sought under the FDCA, which was directly traceable to the plaintiff's illegal conduct and the harm it caused consumers. *Id.* The court distinguished *Philip Morris* by observing that the grant of equity jurisdiction in RICO is much narrower than that in the FDCA. *Id.* at 233. Specifically, the court noted, RICO expressly enumerates specific remedies, all of which are aimed at making it difficult or impossible to violate the Act in the future. *Id.* The FDCA, on the other hand, contains no such list. *Id.*

The only other circuit to address restitution under the FDCA is the Ninth Circuit. In 1956, the court held that restitution is not available under the FDCA in *United States v. Parkinson*, 240 F.2d 918, 922 (9th Cir.1956). The court's decision was based on the statute's failure to explicitly grant courts authority to order restitution. *Id.* The court explained, "[t]he use of the extraordinary remedies of equity in governmental litigation should never be permitted by the courts unless clearly authorized by the statute in express terms." *Id.* The court distinguished *Porter* by noting that the EPCA was enacted in wartime and contained explicit language, specifically the term "other orders," authorizing the use of remedies not enumerated in the statute. *Id.* at 920 & n. 6. The Ninth Circuit's rationale in *Parkinson*, however, was subsequently rejected by the Supreme Court in *Mitchell.* In *Mitchell*, the Court reaffirmed *Porter* in holding equitable remedies need not be expressly authorized by a statute; rather,

a grant of general equity jurisdiction is sufficient to enable a court to exercise all traditional equitable powers absent explicit or implicit evidence to the contrary. *Mitchell*, 361 U.S. at 290-92, 80 S.Ct. 332. Moreover, the Court noted "the applicability of this principle is not to be denied, either because the Court [in *Porter*] considered a wartime statute, or because, having set forth the governing inquiry, it went on to find in the language of the statute affirmative confirmation of the power to order reimbursement." *Id. at 291, 80 S.Ct. 332.* Because *Parkinson's* reasoning was later rejected by *Mitchell*, it is not persuasive. *See Lane Labs, 427 F.3d at 233-34* (rejecting reasoning of *Parkinson*).

IV. Conclusion

For the foregoing reasons, this court **REVERSES** the district court's denial of disgorgement and **REMANDS** the matter for further proceedings not inconsistent with this opinion.

APPENDIX B — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA DATED AND FILED NOVEMBER 4, 2004

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

Case No. 03-CV-0616-EA (M)

UNITED STATES OF AMERICA,

Plaintiff,

v.

RX DEPOT, INC. and RX OF CANADA LLC, corporations, and CARL MOORE and DAVID PEOPLES, individuals,

Defendants.

ORDER

Now before the court are the simultaneous briefs on disgorgement requested by the court and filed on September 27, 2004 (Dkt.. ## 78, 79), Defendants' Motion to Strike Plaintiffs Improper Response to Defendants' Brief in Opposition to Remedy of Disgorgement (Dkt. # 82-1), and Plaintiffs Motion to Publish the Court's Order of August 26, 2004 (Dkt. # 73). After the Court's August 26 Order was entered, the Court requested additional briefs on the propriety of disgorgement of profits where the plaintiff is a government agency; and in particular under the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §§ 301 *et seq.*). In light of

these supplemental authorities, the Court modifies the August 26, 2004 Order, vacating the finding that "disgorgement is the appropriate equitable monetary remedy in this case," finding instead that disgorgement is an inappropriate remedy in this case.

I.

Defendants filed an objection to plaintiff's motion for leave to file a response brief, but the Court granted that motion and defendants were permitted to file a reply This Order considers the arguments made in the simultaneous briefs, as well as in the plaintiff's response and defendants' reply. For this reason, the motion to strike plaintiff's response (Dkt. # 82-1) is **denied.**

II.

Defendants argue that disgorgement is an inappropriate remedy in this case because disgorgement is not explicitly authorized by the statute; because courts have long refused to recognize it as remedy for FDCA violations; and because even those courts recently breaking a long line of precedent refusing to expand upon the, equitable remedies enumerated in the statute have refused to impose disgorgement. The United States argues that the Court's broad powers of equity should only be limited by a "clear and valid legislative command"; that the recent award of restitution in two separate FDCA cases provides sufficient precedent for awarding the equitable remedy of disgorgement; and that disgorgement would serve the purposes of the FDCA by deterring future violators.

This Court's equitable powers extend to granting disgorgement in any situation where there is no "clear and valid legislative command" or "necessary and inescapable inference" limiting such relief. *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291 (1960) (quoting *Porter v. Warner Holding Co.* 328 U.S. 395, 398 (1946)). Further, as the United States points out, the FDCA contains no explicit prohibition of disgorgement, and the FDCA'S injunction provision plainly invokes the Court's equity jurisdiction. Plaintiff's Brief (Dkt. # 79), at 3. However, in exercising its equitable powers in the enforcement of a statute, the Court must carefully consider the context and purposes of the statutory provision before expanding upon the remedies provided therein. Failure to do so would render meaningless any attempt by Congress to legislate statutory remedial schemes:

Statutory Construction

Statutory interpretation should begin with a plain language, ordinary-meaning reading of the statute. *See, e.g., Chickasaw National v. United States*, 208 F.3d 871, 876 (10th Cir. 2000). FDCA section 332 provides jurisdiction to federal courts "to restrain violations of section 331." 21 U.S.C. § 332. This is the only FDCA provision for equity jurisdiction. Courts have not disputed that the language "to restrain" requires remedies under the act to be forward-looking and preventive rather than backward-looking or corrective, though some have argued that restitution and disgorgement may be seen as forward-looking in that the financial burden these remedies place on an FDCA violator

will act to deter future violations.[1] Rather than leaving it at this, however, Congress drafted the FDCA explicitly to provide for certain general remedies: (1) injunctive relief under 21 U.S.C. § 332; (2) criminal prosecution under 21 U.S.C. § 333; and (3) seizure under 21 U.S.C. § 334.

A plain language reading does not indicate a provision for other unenumerated remedies such as disgorgement.[2] To the contrary, the provision of certain other remedies under specific circumstances, under the doctrine of *expressio unius est exclusio alterius*, indicates that their absence among the general remedies provided was intended by Congress. For instance, 21 U.S.C. § 360h(b) gives the FDA the authority to order the repair, replacement, or refund of medical devices that present an unreasonable risk of substantial harm to the consumer. Further, before the imposition of this essentially restitutionary remedy, the provision also requires the FDA to hold an informal hearing at which it must first show certain elements. 21 U.S.C. § 360h(b)(1)(A). The provision of this remedy only in the case of medical devices creates "a necessary and inescapable inference" (such as that sought by the Supreme Court in *DeMario*) restricting the courts' equity jurisdiction with regard to other sections of the FDCA not so providing. *See* Jeffrey N. Gibbs & John R. Fleder,

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1. See section on Judicial Precedent below.

2. Compare the text of §332, which expressly authorizes only injunctions or restraining orders, with the parallel provision (§ 205(a)) in the Emergency Price Control Act of 1942 (EPCA) which expressly authorizes district courts to grant "a permanent or temporary injunction, restraining order, *or other order*." *Porter*, 328 U.S. at 399 (quoting 50 USCA App § 925(a)) (emphasis added).

Can FDA Seek Restitution or Disgorgement?, 58 Food & Drug L.J. 129, 144 (2003) (arguing that this provision creates such an inference).

Similarly, section 333 provides for civil monetary penalties to be assessed against violators of prescription drug marketing regulations or regulations relating to medical devices under certain circumstances. 21 U.S.C. §§ 333(b)(2), 333(f). Disgorgement in an FDCA case, in that it would constitute money paid by the violator into the U.S. Treasury, is really only different from a civil monetary penalty in that the amount would vary from case to case depending on profits made. That Congress has only provided for this disgorgement-like remedy under particular circumstances under the act again creates a "necessary and inescapable inference" that its failure generally so to provide was intentional.

Legislative History

The history of the FDCA provides further evidence that expansion of remedies beyond those enumerated was not contemplated by Congress. Congress enacted section 332 providing for the injunction of violations of federal food and drug law in 1938 to address the apparent inefficiency of the previously granted remedies of seizure or criminal prosecution in the face of "frequent and repeated violations." Charles Wesley Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record* 130, 264, 489, 570 (1938) (reprinting 1934, 1935 Senate Reports, and 1935 House Report on proposed addition of injunctive relief).

Appendix B

Despite the fact that the authors of the amendment intended the new injunctive power to be sweeping in scope, the legislative history of the act made clear to courts that Congress did not intend for it to supercede seizure as the harshest remedy provided by the act. *See United States v. Superpharm Corp.*, 530 F. Supp. 408, 409 (E.D.N.Y. 1981) (court refused to order recall on ground that legislative history indicated Congress intended seizure to be harshest remedy available); Dunn, *Legislative Record* 679, 690, 817-18 (quoting 1937 Senate Reports on "drastic power of seizure" in context of other enumerated enforcement powers and 1938 House Report describing seizure as "harsh remedy [to be] discouraged or confined to cases where public protection requires such action"); *see also* Erika King & Elizabeth M. Walsh, The *Authority of a Court to Order Disgorgement For Violations of the Current Good Manufacturing Practices Requirement of the Federal Food Drug and Cosmetic Act*, 58 Food &Drug L.J. 149, 159-60 (2003) (discussing legislative history of medical device amendments of 1976, Safe Medical Devices Act of 1990, and 1990s legislative proposals as evidence that Congress did not intend disgorgement to be available remedy under the FDCA). *But see* Eric Blumberg, *Universal Management, Abbot, Wyeth, Schering-Plough, and . . . : Restitution and Disgorgement Find Another Home at the Food and Drug Administration*, 58 Food & Drug L.J. 169 (2003) (countering legislative history arguments by focusing on a distillation of the *Porter* and *DeMario* decisions as to the courts' inherent equity powers and emphasizing the three recent consent decrees requiring disgorgement by FDCA violators).

Appendix B

Judicial Precedent

Finally, courts have consistently both rejected disgorgement: as a remedy and held that Congress intended forward-looking, preventive remedies to FDCA violations, such as seizure and permanent injunctions, rather than punitive or arbitrary remedies. *See, e.g., United States v. Ten Cartons*, 888 F. Supp. 381, 404 (E.D.N.Y. 1995) (court rejected disgorgement as punitive and thus inappropriate in FDA enforcement action against seller of an unapproved new drug), *aff'd on other grounds*, 72 F.3d 285 (2d Cir. 1995); *United States v. Superpharm Corp.*, 530 F. Supp. 408, 410-11 (E.D.N.Y. 1981) (court granted permanent injunction against seller of unapproved new drug but refused to grant recall on ground that it was past-looking remedy and so an abuse of court's power); *United States v. Parkinson*, 240 F.2d 918, 919 (9th Cir. 1956) (court granted injunction against misbrander of drug but refused to grant restitution because it would constitute reading remedies into an already enumerated statutory list); *Hygrade Food Prods. v. United States*, 160 F.2d 816, 817-19 (8th Cir. 1947) (court reversed district court imposition of two-year injunction against shipper of contaminated cheese, instead enjoining shipping only until products were made safe on ground that purpose of statute is to protect consumers not to punish wrongful acts).

Even in the two recent cases departing from this rule by awarding restitution against FDCA violators, the courts in question have continued to distance themselves from the remedy of disgorgement. In 1997, an Ohio district judge noted that although the fact that no court had previously ordered

disgorgement in an FDA case was not fatal, it did "cast some doubt on the appropriateness of disgorgement" in that case. *United States v. Universal Mgmt Servs., Inc.*, 999 F. Supp. 974, 980 (N.D. Ohio 1997), *aff'd*, 191 F.3d 750 (6th Cir. 1999). More recently, a New Jersey district judge relied on the Sixth Circuit's affirmation in *Universal Management Services* and the theory that ordering monetary equitable relief would advance the purposes of the FDCA by making violations unprofitable, but did not further address, the propriety of disgorgement, particularly in cases where there are no victims to be compensated by the proceeds.

Although the United States points out that allowing defendants to keep any profits gained through their violative activity is contrary to the preventive purpose of the act in that it might encourage affiliates and others to violate the FDCA until the government is able to bring court actions against each one,[3] the Court concludes that the FDCA itself does not contemplate such a remedy. Taken together, the statutory construction and legislative history present "a necessary and inescapable inference, restricting the court's jurisdiction in equity" as required by the Supreme Court in

3. The FDA's recent use disgorgement through consent decrees represents a significant departure from historic precedents in Many respects and provides little if any precedential value. *See* William W. Vodra & Arthur N. Levine, *Anchors Away: The Food and Drug Administration's Use of Disgorgement Abandons Legal Moorings*, 50 Food & Drug L.J. 1 (2004) (pointing out that the FDA disgorgement agreements have directly and exclusively benefitted the government rather than any victim, have provided for government control of their duration, and have never been subject to judicial scrutiny, in addition to failing to reflect (in amount) any unjust enrichment by the violators).

Porter and *DeMario*. For this reason, the Court finds that disgorgement would be an inappropriate remedy in this case.[4]

For the reasons stated above, defendants' motion to strike plaintiff's response (Dkt. # 82-1) is **denied.** The Court modifies the August 26, 2004 Order (Dkt, # 69), vacating the finding that "disgorgement is the appropriate equitable monetary remedy in this case," finding instead that disgorgement is an inappropriate remedy in this case. Accordingly, plaintiff's motion to publish that Order (Dkt. # 73) is **denied.**

IT IS SO ORDERED this 4th day of November, 2004.

s/ Claire V. Eagan
CLAIRE V. EAGAN
UNITED STATES DISTRICT JUDGE

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4. The parties also raise the questions of whether there are any ill-gotten gains to be disgorged in this case and whether a disgorgement order would constitute a grant of permanent injunctive relief based only on evidence developed in the preliminary injunction stage. Having determined disgorgement to be inappropriate here, the Court does not reach either of these issues.

APPENDIX C — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA DATED AND FILED AUGUST 26, 2004

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

Case No. 03-CV-0616-EA (M)

UNITED STATES OF AMERICA,

Plaintiff,

v.

RX DEPOT, INC. and RX OF CANADA LLC, corporations, and CARL MOORE and DAVID PEOPLES, individuals,

Defendants.

ORDER

On February 23, 2004, Plaintiff's Motion for Summary Judgment (Dkt. # 46) was filed, seeking a permanent injunction and equitable monetary relief in the form of restitution and disgorgement. Motion for Summary Judgment, Dkt. # 46, at 9-19. Defendants claim that plaintiff's motion for permanent injunction is premature and improper and that the restitution demand is improper and unsupported by authority. Def. Resp. Br., Dkt. # 49, at 17. Since the filing of the motion, the parties signed a Consent Decree of Permanent Injunction ("Consent Decree") (Dkt. # 66), which was signed and entered on August 20, 2004. The Consent

Decree provides that "[t]he parties agree to leave to the discretion of this Court the issues of what, if any, equitable relief, including restitution and/or disgorgement, should be awarded to Plaintiff." *Id.* at ¶ 19. The Court now addresses the issues of restitution and disgorgement.[1]

The Complaint for Injunction (Dkt. # 1) states a cause of action against defendants under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* In the Consent Decree the parties agreed, and the Court found, that "defendants violated 31 U.S.C. § 331(t) by importing, or causing to be imported, into the United States drugs that were manufactured in the United States by persons other than defendants, in violation of 21 U.S.C. § 381(d)(1)." Consent Decree, Dkt. # 66, at ¶ 3. The parties also agreed, and the Court found, that defendants violated 21 U.S.C. § 331(d). *Id.* at ¶ 4.

Plaintiff requests that defendants be ordered to pay equitable monetary relief. Motion for Summary Judgment, Dkt. # 46, at 19. Plaintiff proposes that

> defendants would make restitution to individuals who purchased prescription drugs from the defendants' partner Canadian pharmacies through the use of the defendants' services. If profits from the illegal sales of prescription drugs remain after

1. In addition to the Government's argument and authorities in its motion, the Government also filed Plaintiff's Notice of Supplemental Authority (Dkt. # 58) on the issue of equitable relief. The Court has considered the Government's supplemental authority in making its findings.

> the restitution process is exhausted, they would be disgorged. The Court could also order disgorgement sooner if facts revealed through discovery that restitution would be impracticable.

Id. at 19.

Recently, the District of New Jersey addressed the issue of equitable relief in the form of restitution and disgorgement under the FDCA, *United States v. Lane Labs-USA. Inc.*, 2004 U.S. Dist. LEXIS 13277 (D.N.J. July 9, 2004), and provided a detailed and accurate description of the difference between the two:

> Restitution and disgorgement are both equitable remedies. *See Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255, 124 L. Ed. 2d 161, 113 S. Ct. 2063 (1993) (finding that injunctions and restitution are equitable remedies); *SEC v. Hughes Capital Corp.*, 917 F. Supp. 1080, 1085 (D.N.J. 1996) ("Disgorgement of illegally derived funds is a remedy within the equitable powers conferred on [the] Court . . ."), *aff'd*, 124 F.3d 449 (3d Cir. 1997). Restitution is a remedy that restores the status quo by returning to the purchaser the price of unlawfully sold goods. *See Porter v. Warner Holding Co.*, 328 U.S. 395, 402, 90 L. Ed. 1332, 66 S. Ct. 1086 (1946). The primary purpose of restitution is to restore aggrieved parties to the position that existed before the illegal or wrongful transaction occurred by compensating them for loss caused by the conduct. *See Hughes*, 917

> F. Supp. at 1089 (quoting *SEC v. Huffman*, 996 F.2d 800, 802 (5th Cir. 1993)).
>
> Disgorgement is a remedy that requires a defendant to surrender all of its profits from an unlawful transaction to the government. *CFTC v. American Metals Exchange*, 991 F.2d 71, 78-79 (3d Cir. 1993). Disgorgement differs from restitution in that it seeks to force the wrongdoer to give up the amount by which he has been unjustly enriched through illegal profits and does not turn on compensating the victims. *Hughes*, 917 F. Supp. at 1085 ("Disgorgement wrests ill-gotten gains from the hands of the wrongdoer.") (quoting *Huffman*, 996 F.2d at 802).

Id. at *78-79.

Plaintiff seeks both restitution and disgorgement because "[a]llowing the defendants to keep those profits [commissions on sales to new customers and refills on existing customers] would encourage their affiliates and others like them to violate the FDCA until the government is able to bring court actions against each and every operator willing to break the law." Motion for Summary Judgment, Dkt. # 46, at 16. Plaintiff argues that if the Court does not order defendants to pay restitution and/or disgorgement, this outcome "would frustrate the aim of the FDCA and detract from the important 'deterrent effect of the [court's] order, an effect consistent with the FDCA's purpose in protecting the public health.'" *Id.* at 16-17 (quoting *United States v. Universal Mgmt. Serv., Inc.*, 191 F.3d 750, 763 (6th Cir.

1999)). Plaintiff alleges that "[t]o circumvent that law [the FDCA] by illegally importing drugs from outside that system 'is to deceive the public both as purchasers and users' of the drugs." *Id.* (quoting *Universal Mgmt.*, 191 F.3d at 763). Thus, plaintiff claims that restitution is appropriate because the Court can order equitable monetary relief without a demonstration of harm to any particular customer. *Id.* Finally, plaintiff admits that "neither the government nor the defendants (who claim to keep no sales records) know the exact extent to which the defendants' actions have resulted in consumer injury, either physical or economic." *Id.*

Defendants claim that restitution is not appropriate because "[a]s Plaintiff's own authority attests, the purpose of restitution is to 'make the consumer whole.'" Def.. Resp. Br., Dkt. # 49, at 17 (quoting *Universal Mgmt.*, 191 F.3d at 763 (citing *First Penn Corp. v. Fed,. Dep. Ins. Corp.*, 793 F.2d 270, 272 (10th Cir. 1986))). Defendants also rely on *Universal Mgmt.*'s statement that ". . . restitution seeks to remedy the type of economic harm to consumers contemplated by the FDCA. . . ." 191 F.3d at 763. Based upon these holdings, defendants argue that, in this case, restitution would be provided "to the health-care customers who relied on Defendants' facilitation in filling prescriptions with Canadian drug supplies. Such restitution would reimburse the customers for the money they wrongfully lost." Def. Resp. Br., Dkt, # 49, at 18. Therefore, defendants assert that restitution is not appropriate because

> [t]he existence and appeal of the service offered by Defendants was rooted solely and completely in the service's ability to *save* the customers'

> money. It is undisputed that the customers spent less to fill their prescriptions by filling them through Canadian suppliers than they would have through the price gouging American pharmaceutical empire, *not more*. This is not a situation of a loss needing to lie reimbursed, a hole needing to be filled, an injury needing redress. This is in fact the paradox.

Id. (emphasis in original). Defendants also claim that plaintiff's proposed restitution scheme is pragmatically impossible. *Id.* Defendants claim that it would be impossible for defendant Carl Moore ("Moore") to "account for each and every one of the innumerable transactions of Rx Depot outlets and track down each and every former customer." *Id.* at 19. Defendants assert this is especially impractical given that Rx Depot ceased business upon the Court's preliminary injunction order filed in November 2003, and that Moore has suffered a heart attack and moved to Florida. *Id.*

The primary purpose of restitution is to restore aggrieved parties to the position that existed before the illegal or wrongful transaction occurred by compensating them for loss caused by the conduct." *Lane Labs-USA*, 2004 U.S. Dist. LEXIS, at * 78. Although defendants acknowledge that they violated sections of the FDCA, there is no evidence from any individual customer that he or she believes that compensation for a loss caused by defendants is appropriate. In fact, the Court has previously found:

> Because of the high cost of prescription drugs in the United States, some citizens cannot afford their medications at U.S. prices. Defendants

> presented three highly credible witnesses to testify to this effect at the preliminary injunction hearing. These witnesses use or used Rx Depot to purchase their medications at a significantly lower price. Trans. at 38, 162-66, 171-72, and 199-214.

Findings of Fact and Conclusions of Law, Dkt. # 28, at 43. Further, plaintiff has not presented any evidence that it has been contacted by any Rx Depot customers seeking restitution. Therefore, the Court finds that restitution is an inappropriate equitable monetary remedy in this case.

"Disgorgement differs from restitution in that it seeks to force the wrongdoer to give up the amount by which he has been unjustly enriched through illegal profits and does not turn on compensating the victims." *Lane Labs-USA*, 2004 U.S. Dist. LEXIS, at * 79; *see also SEC v. Blatt*, 583 F.2d 1325, 1335 (5th Cir. 1978). It is important to note that Rx Depot has agreed that it violated sections of the FDCA, Consent Decree, Dkt. #66, at 3-4, and the Court has found:

> The fact that there are currently no known cases of someone being harmed by a drug received as a result of using Rx Depot, Trans. at 137-38, or that plaintiff is currently unaware of anyone being harmed by prescription medications ordered through Rx Depot and imported from Canada, Trans. at 85, does not diminish the legitimate safety concerns of the FDA with unregulated commercial reimportation of U.S.-manufactured drugs by someone other than the manufacturer and

importation of foreign-manufactured drugs not approved by the FDA.

Findings of Fact and Conclusions of Law, Dkt. # 28, at ¶ 21. In addition, the Court found that "[d]efendants receive a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. The defendants also receive commissions for refill orders, which generally are arranged directly between customers and the Canadian pharmacies." *Id.* at ¶ 13. Therefore, the Court finds that defendants engaged in wrongdoing and were unjustly enriched through illegal profits. Thus, the Court finds that disgorgement is the appropriate equitable monetary remedy in this case.

"The district court has broad discretion in fashioning the equitable remedy of a disgorgement order." *SEC v. Huffman*, 996 F.2d 800, 803 (5th Cir.1993). At the same time, " [t]he court's power to order disgorgement extends only to the amount with interest by which the defendant profited from his wrongdoing." *Blatt*, 583 F.2d at 1335. The Court is unable at this time to determine the proper amount to disgorge from each defendant because the request for disgorgement was based on the presumption that the Court would also award restitution. *See* Motion for Summary Judgment, Dkt. # 46, at 19. As a result, the Court finds that additional briefing by the parties on the appropriate amount of disgorgement, if any, is necessary. In accordance with this finding, the parties shall submit on or before October 1, 2004, simultaneous briefs on the amount of disgorgement as to each defendant. In addition, upon entry of this Order, defendants shall immediately refrain from disposing of or transferring any assets that may interfere with the implementation of disgorgement.

Appendix C

For the reasons stated above, the Government's request for an award of equitable monetary relief (Dkt. # 46) is **granted in part and denied in part:** it is granted as to disgorgement; it is denied as to restitution. The amount, if any, of disgorgement is **under advisement.**

DATED this 26th day of August, 2004.

s/ Claire V. Eagan
CLAIRE V. EAGAN
UNITED STATES DISTRICT JUDGE